

MEMPHIS, TN 38116

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| APPLICATION NO.                                | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|--|----------------|----------------------|------------------------------|------------------|
| 10/645,962                                     | 08/22/2003     | David Farrar         | 00167-482001 /<br>02-31-0454 | 8400             |
| 26166 7  | 590 10/18/2006 |                      | EXAMINER                     |                  |
| FISH & RICHARDSON P.C.<br>SMITH & NEPHEW, INC. |                | IZQUIERDO, DAVID A   |                              |                  |
| 1450 BROOKS ROAD                               |                | ART UNIT             | PAPER NUMBER                 |                  |
|  |                |                      |                              |                  |

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | Analia ant/a)   |  |  |  |  |
|---|--|---|--|--|--|--|
|   | Application No.  | Applicant(s)  |  |  |  |  |
| 0.65  | 10/645,962   | FARRAR ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit  |  |  |  |  |
|   | David A. Izquierdo   | 3738  |  |  |  |  |
| The MAILING DATE of this communication a Period for Reply   | ppears on the cover sheet wi   | th the correspondence address   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory perions - Failure to reply within the set or extended period for reply will, by state that the period for reply will, by state that the material patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNIO<br>1.136(a). In no event, however, may a rood will apply and will expire SIX (6) MON<br>tute, cause the application to become AB | CATION.  eply be timely filed  ITHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133). |  |  |  |  |
| Status  |  |   |  |  |  |  |
| 1) Responsive to communication(s) filed on 31   | March 2006.  |   |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ T   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |   |  |  |  |  |
| 3) Since this application is in condition for allow   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |   |  |  |  |  |
| closed in accordance with the practice unde   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |  |  |  |  |
| Disposition of Claims   |  |   |  |  |  |  |
| 4) Claim(s) 1,3,4,6-11,22-32,37,38,40,41 and  | ∑ Claim(s) <u>1,3,4,6-11,22-32,37,38,40,41 and 44</u> is/are pending in the application.   |   |  |  |  |  |
| 4a) Of the above claim(s) 2,5,6,12-21,33-36,  | 4a) Of the above claim(s) 2,5,6,12-21,33-36,42,43 and 45-47 is/are withdrawn from consideration.   |   |  |  |  |  |
| 5) Claim(s) is/are allowed.   | 5) Claim(s) is/are allowed.  |   |  |  |  |  |
| •   | Claim(s) <u>1,3,4,8-11,22-26,28-32,37,40,41 and 44</u> is/are rejected.  |   |  |  |  |  |
| •   | Claim(s) 7 and 27 is/are objected to.  |   |  |  |  |  |
| 8) Claim(s) are subject to restriction and  | d/or election requirement.   |   |  |  |  |  |
| Application Papers  |  |   |  |  |  |  |
| 9)☐ The specification is objected to by the Exam  | iner.  | ·   |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |  |   |  |  |  |  |
| Applicant may not request that any objection to t   |  |   |  |  |  |  |
| Replacement drawing sheet(s) including the corr   |  |   |  |  |  |  |
| 11)☐ The oath or declaration is objected to by the  | Examiner. Note the attached  | J Office Action or form PTO-152.  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |   |  |  |  |  |
| 12) ☐ Acknowledgment is made of a claim for fore a) ☐ All b) ☐ Some * c) ☐ None of:   | ign priority under 35 U.S.C. {   | § 119(a)-(d) or (f).  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |  |   |  |  |  |  |
| 2. Certified copies of the priority docume  |  |   |  |  |  |  |
| 3. Copies of the certified copies of the p  | •  | received in this National Stage   |  |  |  |  |
| application from the International Bur  |  | raceived  |  |  |  |  |
| * See the attached detailed Office action for a   | ist of the certified copies hot  | received.   |  |  |  |  |
| Attachment(s)   |  |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892)   |  | Summary (PTO-413)   |  |  |  |  |
| <ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO/SB/08)</li> </ul>   |  | (s)/Mail Date<br>Informal Patent Application  |  |  |  |  |
| Paper No(s)/Mail Date   | 6) 🗌 Other:  | <u>_</u> .  |  |  |  |  |

#### **DETAILED ACTION**

### Response to Arguments

1. Applicant's arguments with respect to claims 1, 3, 4, 7-11, 22-32, 37, 38, 40, 41, and 44 have been considered but are moot in view of the new ground(s) of rejection. Furthermore, claim 3 is no longer withdrawn from consideration because it is drawn to an elected species.

#### Election/Restrictions

2. Claim 6 has withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on August 19<sup>th</sup>, 2005.

## Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4, 8-11, 22-26, 28-32, 37, 38, 40, 41, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Sambrook et al. (WIPO 02/15881) as identified by Applicant within the Information Disclosure Statement.

Sambrook et al. discloses a medical device comprised of two components, a porous ceramic scaffold wherein the pores have a diameter between 20 and 200 microns and the scaffold has a porosity of between 10 percent and 90 percent (page 3, paragraph 3) and a polymeric material

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which fills the pores of the ceramic scaffold wherein the polymeric material comprised a higher rate of degradation than the ceramic scaffold. The combination of the two layer provides a device which is substantially non-porous prior to implantation and allows for the ingrowth of tissue after implantation (page 8, paragraphs 4-5).

- 5. Furthermore, Sambrook et al. discloses a polymeric layer comprising a therapeutic additive comprising a higher rate of degradation than the ceramic scaffold (pages 13-14).
- 6. Regarding claims 29 and 30 Sambrook et al. discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claims, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.

#### Allowable Subject Matter

7. Claims 7 and 27 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **Conclusion**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Izquierdo whose telephone number is 571-272-1943. The examiner can normally be reached on Monday through Friday from 8:00 am until 4:30 pm.

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9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Izquierdo

by charles

TOM BARRETT
PRIMARY EXAMINER
FECHNOLOGY CENTER 3700